

## REMARKS

In the Office Action issued on June 8, 2006, the Examiner:

- made the previously issued Election/Restriction requirement final;
- made a priority determination regarding the effective filing date for the subject matter defined by the claims currently under consideration;
- objected to the specification;
- objected to Claims 9, 10, 20, and 29 for informalities;
- rejected Claims 20 through 22, 27 and 28 as being indefinite under 35 U.S.C. §112, second paragraph;
- rejected all pending claims under the judicially created doctrine of obviousness-type double patenting over Claims 1 through 33 of United States Patent No. 6,200,336, Claims 1 through 21 of United States Patent No. 6,508,833, and Claims 1 through 12 of United States Patent No. 6,974,474;
- provisionally rejected all pending claims under the doctrine of obviousness-type double patenting over Claims 1 through 16 of copending Application Serial No. 09/777,091, Claims 1, 7, and 14 through 25 of copending Application Serial No. 10/721,582, Claims 1 through 19 and 22 through 42 of copending Application Serial No. 10/910,490, Claims 1 through 20 of copending Application Serial No. 11/185,272, and Claims 1 through 29 of copending Application Serial No. 10/828,716;
- rejected Claims 8 through 11, 16, 18, 20 through 22, 27 through 29, and 36 under 35 U.S.C. §102(b) as being anticipated by United States Patent No. 5,855,601 to Bessler ("Bessler"); and
- rejected Claim 17 under 35 U.S.C. §103(a) as being unpatentably obvious over Bessler in view of United States Patent No. 5,713,950 to Cox ("Cox").

The Applicants have fully considered the Office Action and cited references and submit this Reply and Amendment in response to the Examiner's objections and rejections. Reconsideration of the application for patent is requested.

### Initial matter – attorney not of record acting in representative capacity

As an initial matter, please note that the undersigned attorney is not of record and is currently acting in a representative capacity pursuant to 37 C.F.R. §1.34 (See M.P.E.P. §405).

#### Initial matter – status of claims 38 and 39

As an initial matter, the Applicants note the absence of an indication of the status of claims 38 and 39 in the subject Office action. Each of these claims were present in the application when originally filed and in the listing of claims presented in the Amendment filed on November 16, 2005. Applicants have presumed that these claims have been withdrawn from further consideration based on the earlier issued Election/Restriction requirement.

The Applicants respectfully request an indication of the current status of each of these claims, and expressly reserve the ability to request further consideration if in fact they have not been withdrawn.

#### Election/restriction requirement

The Examiner made the previously issued Election/Restriction requirement final. Applicants acknowledge the withdrawal of Claims 1 through 7, 12 through 15, 19, 23 through 26, 30 through 35, and 37 from further consideration. Applications reserve the right to pursue these and other claims in subsequent applications, or in the current application should a generic or linking claim ultimately be allowed.

#### Priority determination

The Examiner indicated that the subject matter defined by Claims 8 through 11, 16 through 18, 20 through 22, 27 through 29, and 36 was not introduced until the filing of provisional application serial number 60/403,783 on August 15, 2002. Based on this indication, the Examiner determined that the effective filing date for the subject matter defined by these claims is August 15, 2002.

Applicants respectfully traverse this characterization by the Examiner. The pending claims find support in disclosures made prior to August 15, 2002. As exemplary support, the Examiner's attention is drawn to Figures 35, 37, and 40, along with the accompanying discussion, in Patent Application Serial No. 09/777,091, filed on February 5, 2001 and published as Patent Application Publication No. 2001/0039450. Reconsideration of the priority determination is requested.

#### Objections to the specification

The Examiner objected to the specification for various informalities. Specifically, the Examiner indicated that, as filed, the BRIEF DESCRIPTION OF THE DRAWINGS lacks a brief description of Figures 1A, 3A, and 3B and that no application serial number is included for the "*Stent and Method of Forming a*

*Stent with Integral Barbs*" application listed in the RELATED APPLICATIONS section.

The Applicants have herein amended the specification to correct both of these informalities. The BRIEF DESCRIPTION OF THE DRAWINGS has been amended to include a description of Figures 1A, 3A, and 3B and the RELATED APPLICATIONS SECTION has been amended to reflect the application serial number for the listed United States application for patent.

Each of these amendments is fully supported by the application as filed and neither adds new matter to the application. The added figure descriptions simply reflect a written description of the drawings present in the application as filed, and the inclusion of the serial number simply reflects identifying information that was unavailable as of the filing date of the present application because the referenced application was filed concurrently with the present application.

Applicants respectfully assert that each of the objections to the specification have been fully addressed and request that these objections be withdrawn.

#### Objections to the claims

The Examiner objected to Claims 9, 10, 20, and 29 for informalities. Specifically, the Examiner objected to Claim 9 for lacking an indication of dependency, and to Claims 10, 20, and 29 for including typographical errors.

Applicants have herein amended Claim 9 to reflect its dependency on Claim 8. This amendment is made simply to add dependency information that was erroneously omitted in the application as filed. This amendment does not change the scope of protection sought.

Applicants have herein amended Claim 20 to correct the typographical error listed by the Examiner. This amendment is made simply to add identifying information relating to the "outer edge" to reflect proper antecedent basis. The identifying information was erroneously omitted in the application as filed. This amendment does not change the scope of protection sought.

Applicants have herein canceled Claims 10 and 29. The objections to these claims, therefore, are moot.

Applicants respectfully assert that each of the objections to Claims 9, 10, 20, and 29 have been fully addressed and request that these objections be withdrawn.

#### Rejection of claims under 35 U.S.C. §112, second paragraph

The Examiner rejected Claims 20 through 22, 27 and 28 as being indefinite under the second paragraph of 35 U.S.C. §112. Specifically, the Examiner indicated that the limitation "the wall of the bodily passage" in Claim 20 lacks

antecedent basis and that the limitation "the plurality of" in Claim 27 lacks antecedent basis.

Applicants have herein amended Claims 20 and 27 to reflect proper antecedent basis for the listed limitations. The amendments are fully supported by the application as filed because they simply add antecedent basis for limitations already in these claims. Furthermore, these amendments do not change the scope of protection sought.

Claims 21 and 22 depend from Claim 20. Accordingly, the indefiniteness of these claims is addressed by the amendment of Claim 20. Similarly, Claim 28 depends from Claim 27 and, therefore, the indefiniteness of this claim is addressed by the amendment of Claim 27.

Applicants respectfully assert that each of the rejections of Claims 20 through 22, 27, and 28 under the second paragraph of 35 U.S.C. §112 have been fully addressed and request that these rejections be withdrawn.

#### Rejection of claims for double patenting over issued United States patents

The Examiner rejected all pending claims for obviousness-type double patenting over claims 1 through 33 of United States Patent No. 6,200,336, claims 1 through 21 of United States Patent No. 6,508,833, and claims 1 through 12 of United States Patent No. 6,974,474.

Prior to the amendments made herein, the claims under current consideration included independent Claims 8, 10, 11, 20, 27, 29, and 36. The Applicants have herein canceled Claims 10 and 29. Furthermore, in consideration of other rejections raised in the subject Office action, the Applicants have herein amended independent Claims 8, 11, 20, 27, and 36. All remaining dependent claims depend from these amended independent claims. Thus, all claims currently under consideration have been amended.

Applicants respectfully assert that all remaining claims define subject matter that is patentably distinct from the subject matter defined by the listed claims of the cited patents. Accordingly, reconsideration of the double patenting rejection is requested.

#### Provisional rejection of claims for double patenting over copending applications

The Examiner rejected all pending claims for obviousness-type double patenting over Claims 1 through 16 of copending Application Serial No. 09/777,091, Claims 1, 7, and 14 through 25 of copending Application Serial No. 10/721,582, Claims 1 through 19 and 22 through 42 of copending Application Serial No. 10/910,490, Claims 1 through 20 of copending Application Serial No. 11/185,272, and Claims 1 through 29 of copending Application Serial No. 10/828,716.

Prior to the amendments made herein, the claims under current consideration included independent Claims 8, 10, 11, 20, 27, 29, and 36. The Applicants have herein canceled Claims 10 and 29. Furthermore, in consideration of other rejections raised in the subject Office action, the Applicants have herein amended independent Claims 8, 11, 20, 27, and 36. All remaining dependent claims depend from these amended independent claims. Thus, all claims currently under consideration have been amended.

Applicants respectfully assert that all remaining claims define subject matter that is patentably distinct from the subject matter defined by the listed claims of the cited copending applications. Accordingly, reconsideration of the provisional double patenting rejection is requested.

#### Rejection of claims under 35 U.S.C. §102(b)

The Examiner rejected Claims 8 through 11, 16, 18, 20 through 22, 27 through 29, and 36 under 35 U.S.C. §102(b) as being anticipated by Bessler. Applicants have herein canceled independent Claims 10 and 29 and amended all remaining independent Claims (specifically, Claims 8, 11, 20, 27, and 36). As described in detail below, Bessler does not anticipate any of the remaining claims, and removal of this rejection is requested.

Bessler is directed to an artificial heart valve. The device includes a cylindrical, self-expandable stent and a flexible valve disposed within the stent. The valve includes a plurality of leaflets that extend from the periphery of the device into the center of the stent. The leaflets coapt at a point within the stent to define a valve opening that allows fluid to flow through the device in only a single direction.

Importantly, the stent does not support the leaflets of the valve member at any point adjacent the valve opening. For example, as best illustrated in Figure 4, the portions of the leaflets 36 that are adjacent the valve opening are not attached to nor disposed adjacent to any portion of the stent 31. This arrangement apparently works for the valve means taught by Bessler, such as porcine aortic valves, fixed allografts and xenografts, and synthetic materials.

The Applicant has herein amended each of the remaining independent claims to indicate that a support element provides support for a leaflet element at a point adjacent the valve opening. These amendments are fully supported by the application as filed. Exemplary support can be found in Figure 84 and the accompanying discussion. No new matter has been introduced.

To anticipate a claim under 35 U.S.C. §102, a reference must disclose each and every limitation of the claim under consideration. A thorough review of Bessler reveals a complete absence of any disclosure of a support element that provides support for a leaflet element at a point within the periphery of the device. Accordingly, Bessler cannot properly serve as an anticipatory reference of

any remaining claim. Removal of these rejections is therefore appropriate.

Rejection of claims under 35 U.S.C. §103(a)

The Examiner rejected Claim 17 under 35 U.S.C. §103(a) as being unpatentably obvious over the combination of Bessler and Cox. Claim 17 depends from independent Claim 11, which has been amended herein to include the limitation that the support frame “supports each of the plurality of leaflets at a point adjacent the orifice”.

As described above, Bessler fails to disclose a support frame that “supports each of the plurality of leaflets at a point adjacent the orifice.” Cox does not cure this defect of Bessler. Accordingly, the combination of Bessler and Cox fails to establish a *prima facie* case of obviousness, which requires the existence of some suggestion or motivation to combine the references, a reasonable expectation of success, and disclosure of each and every element of the claim under consideration.

Reconsideration of Claim 17, in light of the amendment to Claim 11, is requested.

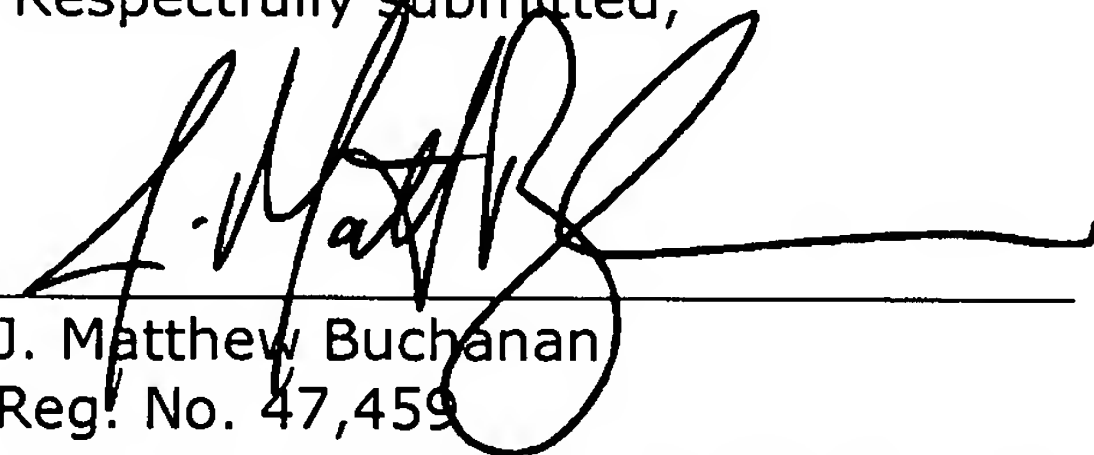


## CONCLUSION

The Applicants have fully responded to the objections and rejections listed by the Examiner in the June 8, 2006 Office Action. The Applicants respectfully assert that all claims currently under consideration define patentable subject matter and that a Notice of Allowability is appropriate.

Should the Examiner have any questions regarding this Reply and Amendment, or the remarks contained herein, the undersigned attorney would welcome the opportunity to discuss such matters with the Examiner.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "J. Matthew Buchanan", is written over a horizontal line. The signature is stylized with large, flowing loops.

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